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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,451	07/25/2003	Jonathan Graff	UTSD:0980	3438

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EXAMINER	
KHARE, DEVESH	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/627,451	GRAFF ET AL.	
	Examiner	Art Unit	
	Devesh Khare	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *18-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *2-13-04* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction is required under 35 U.S.C. 121:

I. Claims 18-20, drawn to a kit comprising an aminoglycoside antibiotic and an associated instructional medium, classified in classes 536 and 424, subclass various.

II. Claims 1-17, drawn to a method of reducing development of colorectal neoplasia in a patient with the composition of Group I, classified in class 514, subclass various.

The inventions are distinct, each from the other because of the following reasons: Groups **I to II** are related as product and process of making. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product can be practiced with another materially different product i.e. a method of reducing development of colorectal neoplasia in a patient can be practiced with another materially different product.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, restriction for examination purposes as indicated is proper.

It is noted that examination of the two independent and distinct inventions would indeed impose an undue burden upon the examiner in charge of this application.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143). If applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims, which depend from or otherwise include all the limitations of the allowable product claim will be rejoined. (MPEP § 821.04)

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

A telephone call was made to Richard Osman on 02/13/04 to request an oral election to the above restriction requirement. During telephone conversation with Richard Osman on 02/18/04, a provisional election was made with traverse to prosecute the invention of Group II, claims 1-17. Affirmation of this election must be made by applicant in replying to this Office action. Claims 18-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 1-17 are currently pending in this application.

35 U.S.C. 112, second paragraph rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(1) Claims 1, 5, 6 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how it is determined that a patient is subject or predisposed to colorectal neoplasia.

(2) The terms: "reducing development of" or "reduced"," poor gut absorption", and "gut-beneficial culture", in all occurrences of this invention, are relative terms, which render the claims indefinite. The terms "reducing development of" or "reduced", "poor gut absorption", and "gut-beneficial culture" are not defined in relation to a method of reducing development of colorectal neoplasia in a patient by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

(3) Claims 11 and 15-17 are vague and indefinite as it is unclear whether the term "microbial culture" is intended to be an anti-neoplasia agent.

Claims which depend from an indefinite claim which fail to obviate the indefiniteness of the claim from which they depend are also seen to be indefinite and are also rejected for the reasons set forth supra.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

35 U.S.C. 103(a) rejection

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> *(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.*

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being obvious over Flotte et al. (Flotte) (U.S. Patent 5,614,502) in view of Hu et al. (Hu) (U.S. Patent No. 6,482,802).

The instant invention is directed to a method of reducing development of colorectal neoplasia in a patient comprising the steps of :
Determining a patient is subject or predisposed to colorectal neoplasia and enterically delivering into the gut of the person an effective amount of an aminoglycoside antibiotic. Additional limitations include: the colorectal neoplasia is non-angiogenin and non-polyposis colon cancer; aminoglycoside antibiotic is one of a plurality of different antibiotics is selected from the group consisting of amikacin, gentamicin, kanamycin, neomycin, netlimicin, paromomycin, streptomycin, and tobramycin; aminoglycoside is other than neomycin; delivery of the aminoglycoside antibiotics in periodic dosages of different subsets of the antibiotics; method further comprises a microbial culture comprises a microbe selected from the group consisting of Lactobacillus, Bifidobacteria, Bacteroides, Streptococcus, and Saccharomyces; determination step is done by detecting polyps or colorectal cancer; and delivery of a constant or varying over time dosage of the aminoglycoside.

Flotte teaches a method of treatment of a disease involving neoplasms by the administration of aminoglycosides (col. 3, lines 25-38). Flotte discloses the aminoglycoside antibiotics such as kanamycin, neomycin, gentamycin, tobramycin, amikacin, netlimicin and streptomycin in combination with high pressure impulse transients, may be useful in the treatment of neoplasia (col. 3, lines 65-68 and col.

4,lines 1-4). (col. 3, lines 9-26 and col. 18,lines 48-60). Flotte differs from the applicant's invention that Flotte does not provide an explicit example of a method comprising the steps of determination of neoplasia and delivery of aminoglycoside to a patient.

Hu teaches a composition comprising neomycin or an analogue and optionally an anti-neoplastic agent and a method for their delivery (abstract). Hu discloses that absorption of neomycin from the intestinal tract is relatively poor and its clinical use is to reduce microbe numbers in the colon prior to colon surgery (col. 5, lines 18-30). Hu discloses that an anti-angiogenic agent of microbial origin is an aminoglycoside antibiotic (col.4, lines 43-45). The determination step in claim 1 is unclear,however Hu discloses a method based on neomycin analogue for inhibiting nuclear translocation of an angiogenic factor (col. 9, lines 34-60). Hu also discloses a list of anti-neoplastic agents in col. 13, lines 1-48. Hu discloses that the said compositions can be administered by any routes used conventionally for drug administration including oral, topical, parenteral and by inhalation (col. 13,lines 49-55).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a method of reducing development of colorectal neoplasia in a patient by the administration of aminoglycosides of the Flotte, in view of the recognition in the art, as evidenced by Hu, that discloses the use of an aminoglycoside antibiotic such as neomycin in a composition and a method of its delivery to a patient. The motivation is provided by Flotte, the prior art suggests the use of aminoglycoside antibiotic such as an neomycin for treating the diseases involving neoplasms and inflammatory processes (col. 3, lines 26-30 and col. 4,lines 1-4).

Any inquiry concerning this communication or earlier communications from the

Examiner should be directed to Devesh Khare whose telephone number is (571) 272-0653.
The examiner can normally be reached on Monday to Friday from 8:00 to 4:30.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, Supervisory Patent Examiner, Art Unit 1623 can be reached at 571-272-0661. The official fax phone numbers for the organization where this application or proceeding is assigned is (703) 308-4556 or 308-4242.
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Devesh Khare, Ph.D.,JD(3Y).
Art Unit 1623
February 20, 2004

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600